Outline Agenda

Issues in the Design of Clinical trials of Transplant Immunuosuppressants for the Prophylaxis/Treatment of Antibody Mediated Rejection (AMR)

A Public Workshop Sponsored by the Food and Drug Administration (FDA)

June 28 & 29, 2010
Crowne Plaza Hotel
8777 Georgia Ave., Silver Spring, MD 20910
Silver Spring, MD

Goals: To elucidate scientific, clinical, and regulatory issues pertaining to antibody mediated rejection to facilitate and encourage the development of therapeutic modalities targeting related indications

First Day	**June 28, 2010**
7:30 – 8:00 am	Registration
8:00 – 8:20 am	**Session 1: Introduction to Regulation and Overview of Topics**
8:25 – 12:00 pm	**Session 2: Diagnostic Characterization of Sensitized Patients** **Speakers:** Howard Gebel Ron Kerman Andrea Zachary Nancy Reinsmoen Michael Amos (NIST) Annette Ragosta (CBER) Kevin Maher (CDRH)
12:00 – 1:00 pm	**LUNCH**
1:00 – 3:15 pm	**Session 3: Diagnostic Criteria for Early Acute AMR** **Speakers:** Robert Colvin Lorraine Racusen Phil Halloran Peter Nickerson Arthur Matas
3:15 – 3:30 pm	**BREAK**
3:30 - 6:00 pm	**Session 4: Treatment and Outcomes in Early Acute AMR** **Speakers:**

	Ergun Velidedeoglu (CDER) John Magee Stanley Jordan Milagros (Millie) Samaniego David Cohen
6:00 pm	**ADJOURN – First Day**
Second Day: June 29, 2010	
7:45 – 7:55 am	Welcome
7:55 – 10:15 am	**Session 5: Endpoints in Trials of Early Acute AMR** **Speakers:** LaRee Tracy (CDER) Dorry Segev Robert Colvin Rosalyn Mannon Herwig-Ulf Meier-Kriesche
10:15 – 12:45 pm	**Session 6: Role of Animal Models in Developing Therapeutics in AMR-Related Indications** **Speakers:** Stuart Knechtle David Sachs Allan Kirk
11:45 - 12:45 pm	**LUNCH**
12:45 – 2:35 pm	**Session 7: Experience with Trial Designs for Desensitization and Prophylaxis of AMR in the Highly Sensitized Patient** **Speakers**: Mark Stegall Steve Woodle Dennis Glotz Robert Gaston
2:35 – 3:45 pm	**Session 8: Discussion of Chronic AMR** **Speakers:** Arturo Hernandez (CDER) Marcello Cantarovich
3:35 – 3:45 pm	Closing Remarks - FDA
3:45 pm	**ADJOURN**